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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,462	08/14/2006	Yukiko Inamoto	2006_1261A	7229

513 7590 02/17/2011

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EXAMINER	
RAO, SAVITHA M	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
02/17/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/589,462	INAMOTO ET AL.	
	Examiner	Art Unit	
	SAVITHA RAO	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-7 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-7and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 4-7 and 9 are pending.

Receipt and consideration of Applicants' amended claim set and remarks/arguments filed on 12/20/2010 is acknowledged. Applicant amended instant claims 4-7 and added new claim 9.

Applicants' arguments, filed 12/20/2010 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Rejection of claims 4-7 and new claim 9 under 35 U.S.C. 103(a) as being unpatentable over Inamoto et al (US 2003/0125308 an English equivalent of WO2001/047525,) as evidenced by Reller (US 4219548) (both references already of record) further in view of Baxter (Nursing Times, Vol.99, No 13, 2003, pages 1-5) is maintained for reasons of record restated below.

New claim 9 is the same as instant claim 4, except it includes the limitation "wherein the medicine does not retard wound-healing".

The references used in the following rejection does not teach the specific effect of acetylsalicylic acid wherein it does not retard wound-healing the combination. However, Inamoto discloses acetylsalicylic acid to be applied to skin injury, such as cut, **wound after operation**, or burn and his preparation is applied directly to the lesion. Accordingly, the aspirin taught by Inamoto et al. has the property of reducing pain, inflammation and itch and would elicit these properties on any type of wounds when

applied since wounds are typically accompanied by pain and inflammation as taught by Baxter. Since the combination of references teach the addition of acetylsalicylic acid topically to heal wounds, it would be obvious that this medicine will not retard wound-healing. Further, this property of aspirin to aid in healing of the wound without retarding wound healing is inherent and will be present in the composition of Inamoto. In addition it is noted that the wounds treated by Inamoto includes wounds resulting from surgery and absence of evidence to the contrary the basic nature of the skin wound after operation is constitutionally same as the skin wound resulting from the infections disease in surgery and as such administration of aspirin to any type of wounds would have the same effect which is anti-inflammatory, anti-itching and pain reduction as recited in the rejection below. It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph). Accordingly, new claim 9 is rendered obvious by the following rejection.

Original Rejection:

Inamoto discloses external preparations having an excellent antipruritic activity acetylsalicylic acid as an active ingredients and a method of treating pruritis by using said external preparations [0001]. Inamoto discloses that acetylsalicylic acid (aspirin) has a strong analgesic activity, antifebrile activity and an antirheumatic activity being

less on its side effects and superior in its safety [0006]. Inamoto also discloses that a new use of acetylsalicylic acid in the form of an external preparation, ointments for treating neuralgia and external preparations for treating skin injury and a transdermal administration system for treatment of thrombosis and prophylactic treatment of cancer has been illustrated in prior art [0008].

Inamoto discloses that the amount of acetyl salicylic acid in the external preparation depends on form of the preparation and is in the range of 0.05-80%, preferably 0.05-70%, more preferably 0.1-50% per total amount by weight. Inamoto additionally discloses that if the aspirin amount is greater than 80% by weight, it is impossible to maintain the physical property of an external preparation and when it is less than 0.05% by weight, there is not enough antipruritic activity and therefore the amount of more than 80% or less than 0.05% is not preferable [0014]. Inamoto teaches examples of diseases with itching for which the external preparation of his invention is used as itching with skin diseases, such as atopic dermatitis, eczema, contact dermatitis etc.; senile pruritis; itching with metabolic diseases, such as hepatocirrhosis etc., itching with endocrine or dyshormonic disease such as diabetes; and itching with skin injury, such as cut, **wound after operation**, or burn [0015]. Inamoto further provides examples of external formulations comprising acetylsalicylic acid (examples 1-25, Tables 1-4, [0027-0030]). Inamoto finally teaches that the preparation as per his invention is applied to the lesion [0025].

Reller is being provided as a supplemental reference to demonstrate the routine knowledge in using acetylsalicylic acid as active ingredient in topical composition that is

useful for the treatment of inflammation of skin including dermatoses accompanied by inflammation, skin injury, contact burns and insect bites (see column 1, lines 18-43; column 1, line 66 through column 2, line 3; Example I-II). Particularly, Example II teaches that topical administration of aspirin is useful in reducing inflammation and the sensation of itching and pain.

Inamoto fails to teach wherein the skin wound is a result of infectious disease in surgery or wound of the vessel and lymphangiopathy

However, Baxter teaches that one of the potential surgical complication is infection (page 4, 2nd paragraph) and **surgical wound infection** (infectious disease after surgery as instantly claimed) is characterized by redness**, pain,** heat and swelling of the wound and periwound and Baxter further teaches that persistence **inflammation** may indicate infection area (page 4, 5th paragraph).

With regards to instant claims 6-7, Inamoto's teachings that the external preparation of his invention comprises acetylsalicylic acid in the concentrations range of 0.05-80%, preferably 0.05-70%, more preferably 0.1-50% per total amount by weight, encompasses the instantly claimed ranges and thereby renders the instant claims obvious. Inamoto's additional teachings that having concentrations less than 0.05% or greater than 80% would not result in a stable composition provides an ordinarily skilled artisan additional motivation to further optimize the concentration to narrow down the dose range, thereby arriving at the instantly claimed concentrations. Additionally, It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is

not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In view of the foregoing references it would have been prima facia obvious to develop a method of treating skin wound and alleviate pain by topical administration of aspirin (acetylsalicylic acid) to the infectious wounds resulting form surgery. Inamoto discloses that acetylsalicylic acid (aspirin) has a strong analgesic activity, use of acetylsalicylic acid in the form of an external preparation for treating neuralgia and external preparations for treating skin injury and further teaches the use of aspirin as a to treat itching associated with sin injury such as wound after operation. Baxter teaches that surgical wound infections are characterized by pain, heat and swelling and inflammation all of which can be treated by aspirin. Accordingly, it would have been obvious to an ordinarily skilled artisan to utilize topical aspirin at the sites of the infected post surgical wounds to reduce pain, decrease inflammation and itching and as such promote healing. A skilled artisan is motivated to do so from the prior art teachings of the pain killing, anti-inflammatory and anti-itch properties of topical aspirin. Further, absent factual evidence to the contrary. “Products of identical chemical composition can not have mutually exclusive properties.” A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).Office lacks laboratory facilities to test the prior art compounds and compositions. Accordingly, the aspirin taught by Inamoto et al. has the property of reducing pain, inflammation and itch and would elicit

these properties on any type of wounds when applied since wounds are typically accompanied by pain and inflammation as taught by Baxter.

Response to applicant's arguments submitted on 12/20/2010

Applicant traverses the above rejection with the following arguments:

a. Inamoto fails to disclose that acetylsalicylic acid is useful for treating a skin wound selected from the group consisting of infectious disease in surgery and vessel and lymphangiopathy, without retarding the healing of the wound. Reller fails to disclose that Aspirin is useful for treating a skin wound selected from the group consisting of infectious disease in surgery and vessel and lymphangiopathy, without retarding the healing of the wound. Baxter fails to suggest Aspirin is useful for treating such wound infections.

b. Unexpected results argument: Applicant's argue that "it is known in the art that medicating a wound with a non-steroidal anti-inflammatory agent actually inhibits wound healing and as such is contraindicated in medicating a wound" and refer to instant specification page 2, lines 2-4). Applicants further refer to Table 9 on page 17 of the specification which recited that indomethacin (a non steroidal anti-inflammatory agent) worsens wound in comparison to the treatment with aspirin. Applicants refer to examples 1,5,10 and 11 of their specification as teaching that Aspirin when applied to the wound regions has effect nearly equal or superior to the effects of conventional commercial wound-healing agent, but does not retard wound-healing.

Applicant's traversal arguments for this rejection have been fully considered, but are not found to be persuasive.

First, it should be noted that the above rejection was made under 35 U.S.C. 103(a) and therefore none of the cited references has to teach every limitation of the instant claims. Applicant is further reminded that the obviousness rejection is not an anticipation rejection. The above mentioned references clearly teach the method of treating a skin wound resulting from various reasons which includes wounds resulting from operations (surgery) with acetylsalicylic acid. The prior art also teaches the benefits offered by using Aspirin in wound treatment which is the anti-inflammatory, anti-pruritic and analgesic effect which helps in wound healing. It is noted that references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the combination of the cited references. *In re Young*, 403 F.2d 754, 159 USPQ 725(CCPA 1968); *In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981).* Moreover, it is noted that rejections under 35 U.S.C. 103(a) are based on combinations of references, where the secondary references are cited to reconcile the deficiencies of the primary reference with the knowledge generally available to one ordinary skill in the art to show that the differences between Applicant's invention and the prior art are such that they would have been modifications that were *prima facie* obvious to the skilled artisan. It is noted that the claimed invention is not required to be expressly suggested in its entirety by any

one or all of the references cited under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In response to applicant's arguments against each reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this instance, Inamoto discloses that acetylsalicylic acid (aspirin) has a strong analgesic activity, use of acetylsalicylic acid in the form of an external preparation for treating neuralgia and external preparations for treating skin injury and further teaches the use of aspirin as a to treat itching associated with sin injury such as wound after operation. Reller is being provided as a supplemental reference to demonstrate the routine knowledge in using acetylsalicylic acid as active ingredient in topical composition that is useful for the treatment of inflammation of skin including dermatoses accompanied by inflammation, skin injury, contact burns and insect bites Baxter teaches that surgical wound infections are characterized by pain, heat and swelling and inflammation all of which can be treated by aspirin. As such the combined teachings of the references provides ample motivation to an ordinarily skilled artisan to use Aspirin in treatment of surgical wound infections which is characterized by pain, heat and swelling .

With regards to the Applicant's argument of unexpected results, Applicants references to the data presented in the instant disclosure has been considered and

found not persuasive.

First the applicants assertion that it is known in the art that medicating a wound with a non-steroidal anti-inflammatory agent actually inhibits wound healing" ,While this may be true for certain NSAIDS such as indomethacin, Prior art teaches Aspirin to have a wound healing effect and not wound retardation effect as evidenced by the prior art of As such use of aspirin in treating skin wounds was well known in the art at the time of invention and it would have been obvious to an ordinarily skilled artisan to use Aspirin in treatment of wounds occurring through different means including infections during surgery with the expectation that it would provide the positive effects to heal the wound as recited by Inamoto and Reller.

With regards to the data in the specification the applicant's relay on, Aspirin used in the experiments was in a specific formulation with several other excipients such as Crotamiton used in examples 1 and 11 and sesame oil used in example 5 etc. Applicants do not disclose the exact formulation of the comparative samples Indomethacin, Bucladesine and Retinoic acid (Table 7) used in the studies. As such, the comparative data does not account for the differences in the final formulation components of each of the agent in the study. Further, the comparative studies are all conducted with specific concentrations of Aspirin ranging at 0.1% to 5%. Finally, the unexpected results are obtained in experiments where in the wound was generated by thermal burn. Accordingly, the unexpected results applicants are claiming was generated with the specific concentration of the Aspirin in specific formulation comprising specific amounts of other excipients on a very specific type of wound

(thermal burns. The instant claims do not recite these limitations required to achieve the unexpected results. For example, instant claim 4 is drawn towards the method of treating a skin wound by administering to the skin wound and effective dose of a medicine comprising aspirin as the active ingredient where in the skin wound is either infectious disease in surgery and vessel and lymphangiopathy. Therefore, the unexpected results observed in these studies are with very specific parameters and are therefore not commensurate with the full scope of what is claimed and the data is not probative of nonobviousness of the full scope of the claims as discussed above.

Accordingly, the arguments set forth by the applicants are unpersuasive and the rejection is maintained.

Conclusion

Claims 4-7 and 9 are rejected. No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7.00 am to 4.00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/
Examiner, Art Unit 1614

/Ardin Marschel/
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